

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	Kenneth M. Adams et al.	Examiner:	Mary C. Hoffman
Serial No.:	10/657,915	Group Art Unit:	3733
Filed:	September 9, 2003	Docket:	M190.145.101 / P0000263.00 US
Due Date:	August 20, 2008		
Title:	SURGICAL MICRO-BURRING INSTRUMENT AND METHOD OF PERFORMING SINUS SURGERY		

APPEAL BRIEF UNDER 37 C.F.R. §41.37

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

This Appeal Brief is submitted in support of the Notice of Appeal filed on June 20, 2008, appealing the final rejection of claims 1-13, 15-24, and 31-36 of the above-identified application as set forth in the Final Office Action mailed January 24, 2008.

The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 50-0471 in the amount of \$510.00 for filing a Brief in Support of an Appeal as set forth under 37 C.F.R. § 41.20(b)(2). At any time during the pendency of this application, please charge any required fees or credit any overpayment to Deposit Account No. 50-0471.

Appellant respectfully requests consideration and reversal of the Examiner's rejection of pending claims 1-13, 15-24, and 31-36.

Appeal Brief to the Board of Patent Appeals and Interferences

Applicant: Kenneth M. Adams et al.

Serial No.: 10/657,915

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Title: SURGICAL MICRO-BURRING INSTRUMENT AND METHOD OF PERFORMING SINUS SURGERY

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REAL PARTY IN INTEREST

The intellectual property embodied in the pending application is assigned to Medtronic, Inc. of Minneapolis, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellant is unaware of other prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in this Appeal.

STATUS OF CLAIMS

In the Final Office Action mailed January 24, 2008, claims 1-13, 15-24, and 31-36 were rejected. Claims 1-13, 15-24, and 31-36 remain pending in the application and are the subject of the present Appeal. Appellant notes that no specific ground of rejection was provided for claim 33 in the Final Office Action. For purposes of Appeal, Appellant assumes that claim 33 stands rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,503,263 to Adams ("the Adams '263 Patent") in view of U.S. Patent No. 6,280,443 to Marino et al. ("Marino").

STATUS OF AMENDMENTS

No Amendments have been entered subsequent to the Final Office Action mailed January 24, 2008. However, an Advisory Action dated April 16, 2008, acknowledged that the Declaration filed September 9, 2003, was accepted.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Discussions about features of claim 1 can be found *at least* at the cited locations in the specification and drawings.

Claim 1 relates to a surgical micro-burring instrument 10, for example as shown in FIGS. 1 and 2, comprising an outer tubular member 18 having a proximal section 40, an intermediate

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section 42, a distal section 44, and a central lumen 46 extending from the proximal section 40 to the distal section 44 (*specification, page 5, line 14 to page 6, line 9*). The distal section 44 forms a pocket 48 fluidly connected to the central lumen 46 (*specification, page 6, lines 9-11*) and includes a bottom surface 72 and an opposed upper opening 78 (*specification, page 7, lines 4-6*). The distal section 44 also includes an elevator tip 62 that extends distal the pocket 48 and a proximal portion 60 that is proximal the pocket 48 and forms a tube (*specification, page 6, lines 26-27*). The pocket 48 is defined by a side wall 70 having an upper edge 82 including a proximal zone 84 extending from the proximal portion 60, an intermediate zone 86 extending from the proximal zone 84, and a distal zone 88 extending from the intermediate zone 86 to a distal-most end of the pocket at which the central lumen 46 terminates (*specification, page 7, lines 8-12*). Relative to an orientation of the outer tubular member 18 in which the bottom surface 72 is the lowest-most surface of the pocket 48, the proximal zone 84 extends downwardly from the proximal portion 60 toward the bottom surface 72, the intermediate zone 86 extends from the proximal zone 84 at an angle of extension relative to the proximal zone 84 that differs from an angle of extension of the proximal zone 84 relative to the proximal portion 60 and the distal zone 88 extends downwardly from the intermediate zone 86 toward the bottom surface 72 at an angle of extension differing from the angle of extension of the intermediate zone 86 relative to the proximal zone 84 (*specification, page 7, lines 12-24*). An inner tubular member 22 is rotatably received within the central lumen 46, and a distal end of the inner tubular member forms a bur 24 positioned within the pocket 48 (*specification, page 5, lines 16-23*). Upon final assembly, at least a portion of the bur 24 is exposed relative to the outer tubular member 18 via the upper opening 78 of the pocket 48.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

I. First Grounds of Rejection

Whether claims 1-13, 17, 22, 23, 33, and 36 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over the Adams '263 Patent in view of Marino.

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II. Second Grounds of Rejection

Whether claims 15, 16, and 34 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over the Adams '263 Patent and Marino, and further in view of U.S. Patent No. 6,214,009 to Toriumi et al. ("Toriumi").

III. Third Grounds of Rejection

Whether claims 18-21 and 35 were properly rejected under 35 U.S.C. §103(a) as being unpatentable over the Adams '263 Patent and Marino, and further in view of U.S. Patent No. 6,312,438 to Adams ("the Adams '438 Patent").

IV. Fourth Grounds of Rejection

Whether claim 24 was properly rejected under 35 U.S.C. §103(a) as being unpatentable over the Adams '263 Patent and Marino and further in view of U.S. Patent No. 5,364,395 to West, Jr. ("West").

ARGUMENT

I. Applicable Law

Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. *MPEP* §2141. The examiner bears the burden under 35 U.S.C. §103 in establishing a *prima facie* case of obviousness. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some additional rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex, Inc.*, 82 USPQ2d 1385, 1396 (U.S. 2007); *In re Khan*, 78 USPQ2d 1329 (Fed. Cir. 2006). In this regard, identification of a teaching, suggestion, or motivation for modifying a reference or combination of the teachings of multiple references provides helpful insight. *KSR* at 1396. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."

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Leapfrog Enterprises, Inc. v. Fischer-Price, Inc., 82 USPQ2d 1687, 1690-1691 (Fed. Cir. 2007). A prior patent cited as a §103 reference must be considered in its entirety, “i.e., as a whole, including portions that lead away from the invention.” *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987). That is, the examiner must recognize and consider not only the similarities, but also the critical differences between the claimed invention and the prior art as one of the inquiries pertinent to any obvious inquiry under 35 U.S.C. §103. *In re Bond*, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990).

II. Claims 1-13, 17, 22, 23, 31, 32, and 36 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over the Adams ‘263 Patent in view of Marino.

A. Claimed Pocket Configuration

Claim 1 recites features of a pocket that render a micro-burring instrument highly amenable for use with a bur. One non-limiting example of the construction is provided in FIG. 3A, which is reproduced below. In particular, claim 1 recites that the pocket is defined by a side wall having an upper edge including a proximal zone, an intermediate zone, and a distal zone. Relative to an orientation in which a bottom surface of the pocket is the lowest-most surface thereof, the proximal zone extends downwardly from a proximal portion of the outer tubular member (e.g., at an angle α). The intermediate zone extends from the proximal zone at an angle differing from that defined by extension of the proximal zone (e.g., linearly with respect to axis A). Finally, the distal zone extends downwardly from the intermediate zone at a differing angle terminating at a distal-most end of the pocket. With this structural arrangement, the pocket exposes a significant circumferential surface of the bur for interacting with tissue.

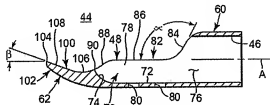


Fig. 3A

B. The Adams '263 Patent Pocket Configuration

The differing zones/extensions set forth in claim 1 are markedly different from the uniform window wall 39 resulting in the relatively small windows 38, 62 illustrated in FIGS. 3B and 4B, respectively, of the Adams '263 Patent. FIG. 3B of the Adams '263 Patent is reproduced below. As illustrated and described, cutting window 38 tapers distally with only a single angle θ , defined by a cutting window wall 39. The wall is designed to project outwardly for engaging and/or dissecting tissue (*The Adams '263 Patent, col. 4, lines 5-21*). In fact, the relatively small cutting window associated with the Adams '263 Patent renders the design inappropriate for bur-type applications. Since the Adams '263 Patent does not envision the use of a bur, one of skill in the art would have no reason to depart from the singular, angular cutting window reflected in FIGS. 3B and 4B.

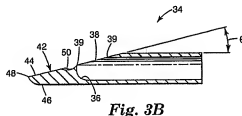


Fig. 3B

C. Marino Pocket Configuration

Marino, otherwise relied upon in the Office Action as teaching a bur useful with the device disclosed in the Adams '263 Patent, is also limited. In particular, the bur 16 of Marino provides cutting teeth 32 only at an interior surface thereof as shown in FIG. 6. With this construction, operation of the Marino tissue resector entails complete proximal retraction of the bur 16 from the window 15, followed by insertion of a facet joint 18 within the window 15. Subsequently, the bur 16 is distally advanced to internally resect the facet joint 18. As best shown in FIG. 2 (reproduced below), then, the wall edge 17 has a downwardly extending proximal segment, a linear intermediate segment, and an upwardly extending distal segment.

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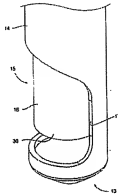


FIG. 2

Marino requires this construction to provide a closed end 13 that prevents the distal end 21 of the bur 16 from contacting tissue (*Marino at col. 2, lines 56 to col. 3, line 3*). Thus, one of skill in the art, upon reviewing Marino would, at best, understand to modify the cutting window 38 of the Adams '263 Patent such that a distal region/zone of the window's edge extends upwardly, in direct contrast to features of claim 1.

D. Reliance of Office Action on *In re Dailey and Eilers* is Misplaced

In rejecting claim 1 as being unpatentable over the Adams '263 Patent in view of Marino, the Office Action acknowledges that the Adams' 263 Patent "fails to disclose the specific shape/configuration of the pocket region" as claimed. To address this deficiency, the Office Action summarily concludes that the claimed shape/configuration of the pocket "is one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a pocket region". The Office Action cites *In re Dailey and Eilers*, 149 USPQ 47 (1966), in support of using numerous shapes or configurations of a pocket region.

In re Dailey related to a patent for disposable nursing containers for infants, with the patent-at-issue reciting claim limitations directed toward a plastic nursing container with a bottom section having a shape that readily collapses upon withdrawal of container contents, in combination with a nipple having a particular slit configuration. The combination nipple and container was discussed at length in the *In re Dailey* Opinion. In addition, the Opinion made passing reference to a dependent claim reciting that the bottom section of the container was "a

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portion of a sphere less than a hemisphere.” It is to this relatively generic claim language (i.e., “a portion of a sphere less than a hemisphere”) that the passage of *In re Dailey* now relied upon by the Office Action is relevant. That is to say, the holdings of *In re Dailey* relating to “mere matter of choice” appear applicable only to a claim limitation of “less than a hemisphere.” In contrast, the pending claims relate to surgical micro-burring instruments, and recite various details directed toward a structural configuration of the pocket. For example, claim 1 provides that the pocket:

- includes a side wall having a proximal zone, an intermediate zone, and a distal zone;
- the proximal zone extends downwardly from the proximal portion [of the outer tube] toward the bottom surface;
- the intermediate zone extends from the proximal zone at an angle of extension relative to the proximal zone that differs from an angle of extension of the proximal zone relative to the proximal portion; and
- the distal zone extends downwardly from the intermediate zone toward the bottom surface at an angle of extension differing from the angle of extension of the intermediate zone relative to the proximal zone.

Clearly, the subject matter and above-highlighted claim features are distinct from the facts of *In re Dailey*. The relatively generic phrase of “less than a hemisphere” is simply not comparable to one or more (or all) of the limitations of claim 1 identified above. Under these circumstances, the Examiner may not rely upon *In re Dailey* in formulating an obviousness rejection. *MPEP §2144*. In fact, *In re Dailey* has not been cited in any subsequent, published Board of Patent Appeals or Court of Appeals for the Federal Circuit decision.

E. The Combination of the Adams ‘263 Patent and Marino Fail to Teach or Reasonably Make Obvious Claim 1

In light of the above, it is respectfully submitted that claim 1, as well as all claims depending therefrom, are not made obvious by the Adams ‘263 Patent in view of Marino. The Adams ‘263 Patent clearly does not teach multiple limitations of claim 1 that are in no way addressed by Marino; the Final Office Action directly concedes this deficiency. Furthermore,

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rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rationale underpinning to support the legal conclusion of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007). In order to sustain a rejection based on “design choice,” the Examiner must provide reasoning why a specific feature is a matter of design choice and therefore obvious. *In re Chu*, 36 USPQ2d 1089 (Fed. Cir. 1995). The Office Action fails to provide any explanation, explicit or otherwise, as to how the specific limitations of claim 1 relating to the pocket would have been obvious to one of skill.

In fact, by characterizing the pocket structural configuration of claim 1 as being “one of numerous shapes or configuration,” it appears that the Examiner is improperly applying an “obvious to try” rationale in support of the obviousness rejection. According to the Final Office Action’s theory, what would have been “obvious to try” would have been to vary all parameters of the pocket-forming structure to try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gives no indication of which parameters are critical and no direction as to which of many possible choices is likely to be successful. Under these circumstances, a *prima facie* case of obviousness cannot be maintained. *MPEP §2145.X*. Still further, Marino, relied upon for teaching use of a bur, teaches away from utilizing a downwardly extending distal zone as claimed. For at least the above reasons, reversal of the rejection of claim 1 is respectfully requested.

F. The Combination of The Adams ‘263 Patent and Marino Fail to Teach or Reasonably Make Obvious Claim 33

Claim 33 provides that the distal-most end of the pocket is below a central axis of the lumen of the outer tubular member. FIGS. 3B and 4B of the Adams ‘263 Patent clearly do not teach this feature. Further, Marino teaches an entirely closed pocket configuration, thus leading one of skill away from the features of claim 33. Pointedly, the configuration of claim 33 facilitates desired exposure of the bur, a structural characteristic not envisioned by the Adams

'263 Patent, and in direct opposition to the bur device of Marino. For at least these reasons, the rejection of claim 33 should be reversed.

G. The Combination of The Adams '263 Patent and Marino Fail to Teach or Reasonably Make Obvious Claim 36

Claim 36 recites that the bur is configured to remove hard bone with rotation of the inner tubular member. In contrast, the micro-shaving or resecting instrument of the Adams '263 Patent, and in particular the cutting tip 150, is not a bur and thus is not capable of removing hard bone. The inventors of the present application specifically averred to this drawback of the Adams '263 Patent (*specification at page 2, lines 14-24*). Thus, claim 36 further defines over at least the Adams '263 Patent and the rejection of claim 36 should be reversed.

III. Claims 15, 16, and 34 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over the Adams '263 Patent and Marino, and further in view of Toriumi.

Claims 15, 16, and 34 are allowable at least based on their relation to claim 1. Thus, the rejection to these claims should be reversed.

IV. Claims 18-21, and 35 were improperly rejected under 35 U.S.C. §103(a) as being unpatentable over the Adams '263 Patent and Marino, and further in view of Adams '438 Patent.

A. Claims 18-21

Claims 18-21 are allowable at least based on their relation to claim 1. Thus, the rejection to these claims should be reversed.

B. Claim 35

Claim 35 recites that the upper edge of the pocket is shaped such that when the bur is distally-most positioned, the axial opening provided by the bur is unobstructed by the outer

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tubular member. With this construction, then, irrigation fluid is readily passed through and exteriorly expelled from the bur, with the flow thereof being unobstructed by the walls otherwise defining the pocket. In contrast, the micro-resecting instrument of the Adams '263 Patent provides a radially-open cutting implement (i.e., the cutting tip 150 is radially open), such that axial flow of fluid is of no concern. As a result, the Adams '263 Patent does not teach the pocket configuration of claim 35. Marino is even further removed, teaching a circumferentially closed distal pocket end. Thus, claim 35 recites additionally allowable subject matter, and its rejection should be reversed.

V. Claim 24 was improperly rejected under 35 U.S.C. §103(a) as being unpatentable over the Adams '263 Patent and Marino and further in view of West.

Claim 24 is allowable at least based on its relation to claim 1. Thus, its rejection should be reversed.

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CONCLUSION

Appellant submits that the Examiner has presented the best available references against the claimed subject matter of the pending application. Reversal of the rejections of claims 1-13, 15-24, and 31-36 is respectfully requested.

Any inquiry regarding this Appeal Brief should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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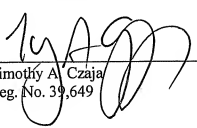
Respectfully submitted,

Kenneth M. Adams et al.,

By their attorneys,

Date: August 27, 2003

TAC:TRF:jms



Timothy A. Czaja
Reg. No. 39,649

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CLAIMS APPENDIX

1. A surgical micro-burring instrument comprising:
 - an outer tubular member having a proximal section, an intermediate section, a distal section, and a central lumen extending from the proximal section to the distal section, the distal section forming:
 - a pocket fluidly connected to the central lumen, the pocket having a bottom surface and an opposed upper opening,
 - an elevator tip extending distal the pocket,
 - a proximal portion proximal the pocket, the proximal portion forming a tube, wherein the pocket is defined by a side wall having an upper edge including a proximal zone extending from the proximal portion, an intermediate zone extending from the proximal zone, and a distal zone extending from the intermediate zone to a distal-most end of the pocket at which the central lumen terminates,
 - and further wherein relative to an orientation of the outer tubular member in which the bottom surface is the lowest-most surface of the pocket:
 - the proximal zone extends downwardly from the proximal portion toward the bottom surface,
 - the intermediate zone extends from the proximal zone at an angle of extension relative to the proximal zone that differs from an angle of extension of the proximal zone relative to the proximal portion,
 - the distal zone extends downwardly from the intermediate zone toward the bottom surface at an angle of extension differing from the angle of extension of the intermediate zone relative to the proximal zone;
 - and
 - an inner tubular member rotatably received within the central lumen, a distal end of the inner tubular member forming a bur positioned within the pocket, such that upon

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final assembly, at least a portion of the bur is exposed relative to the outer tubular member via the upper opening of the pocket.

2. The instrument of claim 1, wherein the elevator tip distally extends at least 0.05 inch relative to the distal-most end of the pocket.
3. The instrument of claim 2, wherein the elevator tip includes an upper surface extending from the distal-most end of the pocket, the upper surface including a proximal region and a distal region, wherein at least a portion of the distal region extends from the proximal region in an angular fashion in longitudinal cross-section.
4. The instrument of claim 3, wherein the angular extension of the distal region defines an included angle in the range of 10° – 50° relative to a central axis of the outer tubular member.
5. The instrument of claim 4, wherein the included angle is approximately 20° .
6. The instrument of claim 4, wherein the included angle is approximately 40° .
7. The instrument of claim 3, wherein at least a portion of the proximal region of the upper surface of the elevator tip extends downwardly from the distal-most end of the pocket.
8. The instrument of claim 7, wherein the proximal region is curved in longitudinal cross-section.
9. The instrument of claim 1, wherein the elevator tip terminates in a distal end point, and further wherein the distal end point is laterally above the distal-most end of the pocket when the outer tubular member is oriented such that the bottom surface of the pocket is below the upper opening.

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10. The instrument of claim 1, wherein the proximal zone extends from the proximal portion in an angularly downward fashion.

11. The instrument of claim 10, wherein angular extension of the proximal zone defines an included angle in the range of 100°– 140° relative to a central axis of the proximal portion.

12. The instrument of claim 11, wherein the included angle is approximately 120°.

13. The instrument of claim 1, wherein the intermediate zone is parallel with a central axis of the proximal portion.

14.(Cancelled)

15. The instrument of claim 1, wherein the bottom surface forms at least one opening fluidly connected to an irrigation source.

16. The instrument of claim 15, further comprising:
an irrigation tube extending exteriorly along the outer tubular member and fluidly connected to the at least one opening.

17. The instrument of claim 1, wherein upon final assembly, a distal end of the bur is longitudinally spaced from the distal-most end point.

18. The instrument of claim 1, further comprising:
an aspiration passage extending through the outer tubular member for aspirating cut tissue.

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19. The instrument of claim 18, wherein the inner tubular member forms a lumen defining the aspiration passage with the bur forming an opening at a distal end thereof, and further wherein the opening is in fluid communication with the lumen of the inner tubular member.

20. The instrument of claim 1, wherein the intermediate section of the outer tubular member defines a longitudinal bend.

21. The instrument of claim 20, wherein the longitudinal bend is approximately 12° relative to a central axis defined by the proximal section.

22. The instrument of claim 1, wherein the instrument is adapted for use in a septoplasty procedure.

23. The instrument of claim 1, wherein the elevator tip is selectively axially moveable relative to the bur.

24. The instrument of claim 23, further comprising:
an intermediate tubular member co-axially disposed between the inner tubular member and the outer tubular member, the intermediate tubular member forming a distal window through which at least a portion of the bur is exposed;
wherein the outer tubular member is slidably received over the intermediate tubular member.

25. – 30.(Cancelled)

31. The instrument of claim 1, wherein the bur forms a plurality of cutting flutes.

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32. The instrument of claim 1, wherein the bur has a shape selected from the group consisting of cylindrical, spherical, hemispherical, ellipsoidal, and pear.
33. The instrument of claim 1, wherein the distal-most end is below a central axis of the central lumen when the outer tubular member is spatially oriented such that the bottom surface is a lowest-most surface of the pocket.
34. The instrument of claim 1, wherein the bottom surface forms a plurality of ports opposite the upper opening.
35. The instrument of claim 19, wherein the distal end opening formed by the bur is in an axial opening, and further wherein the upper edge is shaped such that when the bur is in a distal-most position relative to the distal-most end of the pocket, the opening is unobstructed by the outer tubular member.
36. The instrument of claim 1, wherein the bur is configured to remove hard bone with rotation of the inner tubular member.

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EVIDENCE APPENDIX

All the evidence related to this Appeal is on the record and before the Board. Therefore, no additional evidence is identified in this Appendix.

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RELATED PROCEEDINGS APPENDIX

There are no additional related proceedings to be considered in this Appeal. Therefore, no such proceedings are identified in this Appendix.